



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/537,391

06/02/2005

Fukuya Hiroshi

10921.324USWO

1191

52835

7590

09/19/2008

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.

P.O. BOX 2902

MINNEAPOLIS, MN 55402-0902

EXAMINER

LOUIE, MANDY C

ART UNIT

PAPER NUMBER

1792

MAIL DATE

DELIVERY MODE

09/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,391	Applicant(s) HIROSHI ET AL.	
	Examiner MANDY C. LOUIE	Art Unit 1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/02/2005, 02/09/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The instant claims are drawn to a method of manufacturing an analytical tool, which comprises a reagent forming method by providing a base plate with a reagent member formed from a material liquid that contains a reagent that will react with a specific component of a sample liquid; and the reagent forming method further comprising a plurality of applying and drying steps where the material liquid is applied and then is dried. Further limitations are then described by the dependent claims.

5. Claims 1, 3, 5, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiratsuka et al. [US 4753531] in view of Greenstein [US 4025669].

Regarding claim(s) 1, Hiratsuka et al. teaches an analytical instrument for detecting the presence of an analyte (specific component) from a liquid sample [abstract] where the liquid sample is introduced into a reaction chamber of the instrument [column 4, lines 6-9]. Hiratsuka et al. discloses a reagent, which reacts with the analyte contained in the liquid sample [column 4, lines 15-19], and discusses various methods of forming a reagent member where the reagent can also be coated on the inner wall of the reaction chamber, where the reagent may be in dry form (solid), semidry form (jelly), or liquid form for rapid reaction between the reagent and the analyte [column 4, lines 22-29]. The reaction chamber is within the container part (11) [column 3, lines 22-23], where the container part is described as plate form [column 3, lines 14-15]. It would have been readily apparent to one with ordinary skill in the art to view the plate form container part (11), in light of figures 1& 2, as the base plate to support and contain the reagent member. It would have also been understood to one with ordinary skill in the art that a reagent in liquid form would consist of suspending the

Art Unit: 1792

reagent in a solvent (liquid material) for liquid dispensing methods. Although coating a reagent onto the container part is disclosed, Hiratsuka et al. fails to teach a plurality of steps of applying and drying to form a reagent member where a liquid material containing a reagent is applied and the liquid material is dried to form the reagent member. Greenstein teaches this deficiency.

Regarding claim 1, Greenstein teaches a multiple pass method of applying printing paste upon a substrate [abstract], where a first coat of the paste is applied to a substrate, and the substrate subsequently heated to remove the solvent of the paste. The paste application and substrate heating steps in sequence can each be repeated at least one additional time [column 3, lines 54-60]. It would have been readily apparent to one with ordinary skill in the art that a multiple pass method comprises a plurality of applying and drying steps, and that this method can be substituted with a liquid material containing a reagent to coat a container part (substrate) and dry in a series of repeated coating and drying steps to reach a desirable thickness for a reagent member. It would have also been understood to one with ordinary skill in the art that the multiple pass method utilized a liquid vehicle means of conveying a mixed solution to a surface, in other words, using a liquid dispensing method to form a film on a surface.

Regarding claim 3, Hiratsuka et al. in view of Greenstein teaches the plurality of applying and drying steps are repeated several times (e.g. 2-8 times) until a desirable thickness is achieved [column 9, lines 28-30]. It would have been recognizable to one with ordinary skill in the art that the number of times of applying and drying is

Art Unit: 1792

determined by the desired thickness of the coating; and thus, the steps can be repeated more than as exemplified by the prior art.

Regarding claim 5, Hiratsuka et al. in view of Greenstein teaches an analytical instrument where the base plate (container part) comprises a reagent holding portion formed as a recess (reaction chamber) including a bottom and side surfaces (internal walls of the reaction chamber) where the reagent member is formed in contact with the bottom surface as shown in figures [Hiratsuka et al., figures 1a, 1b].

Regarding claim 13, Hiratsuka et al. in view of Greenstein teaches the drying step is supplied by heat energy [Greenstein, column 4, lines 3-7].

Regarding claim 15, Hiratsuka et al. in view of Greenstein teaches heating the substrate (base plate) to dry a coating on the substrate [column 4, lines 3-4]. Hiratsuka et al. in view of Greenstein also teaches that an oven provided with infrared lamps or *other heating means* are provided to heat the ceramic base (1) (base plate) to dry the coating on the base [column 10, lines 61-67]. It would have been apparent to one with ordinary skill in the art that heating a substrate may also include providing a heat source in contact with the base in order to effectively dry the coating located on the opposite side of the base plate. In this case the base is placed in a heating chamber in an arrangement in which the base is faced downward with the coating is faced upward, to prevent any irregularities to the coating by omitting physical contact and thus, requiring the base to be in direct contact with the heating chamber. Heating the backside of a substrate with direct contact with a heat source is known in the art of coating processes.

It would have been obvious to one with ordinary skill in the art at the time of the invention to apply Hiratsuka et al. with Greenstein to use a multiple pass printing method to form the reagent member. One would have been motivated to do so to minimize the flow of the paste unto unwanted areas [Greenstein, column 15, lines 3-5], with each layer of coating uniformed wettness in the absence of above atmospheric pressures without any irregularities being formed [Greenstein, column 15, lines 24-26], and in addition to having stable viscosities over a period of time which would be economical for operational purposes [Greenstein, column 15, lines 48-50].

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiratsuka et al. in view of Greenstein as applied to claim 1 above, and further in view of Renn [US 3975162].

Teachings of Hiratsuka et al. in view of Greenstein is aforementioned. Hiratsuka et al. in view of Greenstein fails to teach the material liquid contains 0.1-60 wt% of a reagent. Renn teaches this deficiency.

Regarding claim 4, Renn teaches a method of applying a reagent in solution (liquid material) to a surface to form a film device [abstract], where the relative proportions of reagent and water-soluble binder (liquid material) in the device can vary depending upon the size or amount of the measured quality which is desired and is a matter of choice or convenience; but usually in amounts of 10-95wt % of binder while the reagent constitutes the remainder (percentages) [column 2, lines 48-56]. It would have been understood to one with ordinary skill in the art that the remaining percentages for the reagent can vary from 5-90wt%. Furthermore, Renn also supports

Art Unit: 1792

that a liquid material containing a reagent is capable of being formed into a film or coating.

It would have been obvious to one with ordinary skill in the art at the time of the invention to apply Renn with Hiratsuka et al. in view of Greenstein to have a material liquid contain 0.1-60wt% of the reagent. One would have been motivated to do so to form thin layers of reagent containing materials [Renn, column 3, lines 31-33], while having the reagent be distributed as uniformly as possible through out the solution [Renn, column 2, lines 60-64], and have the film remain in place on a surface until reaction between the liquid sample has completed [Renn, column 3, lines 46-49].

7. Claims 2, and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiratsuka et al. in view of Greenstein as applied to claim 1 above, and further in view of Bass [US 6420180B1].

Teachings of Hiratsuka et al. in view of Greenstein is aforementioned. Hiratsuka et al. in view of Greenstein fails to teach where the plurality of applying and drying are performed with a material liquid containing a same reagent (claim 2); where the material liquid is applied with an inkjet-type dispenser (claim 10); and the dispenser can dispense a droplet of 10-2000pL in such a manner that a plurality of droplets can be attached to an application target portion (claim 11). Bass teaches these deficiencies.

Regarding claim 2, Bass teaches a method for multiple pass deposition of chemical array fabrication where a reagent drop set is deposited during a cycle and the step is repeated as required, and the drops the same reagent can be deposited from different deposition units during the same cycle [abstract]. Bass further discloses that it

is known to use multiple firings of a same reagent from the same pulse jet during the same cycle [column 3, lines 6-8].

Regarding claim 10, Bass teaches the printing head can be an ink jet type dispenser [column 9, lines 54-55].

Regarding claim 11, Bass teaches that amount of fluid dispensed can range about 0.1 to 1000 pL, and that it would be well known in the art to control the amount of liquid dispensed by changing a number of parameters [column 10, lines 12-20]. A reagent drop set is deposited during a cycle so as to attach a corresponding moiety for that address (target location) [column 3, lines 24-25], where a set of drops may contain one or more drops [column 5, lines 61-62], and is exemplified by a reagent drop set of four drops for a target feature [column 8, lines 11-14].

It would have been obvious to one with ordinary skill in the art at the time of the invention to apply Bass with Hiratsuka et al. in view of Greenstein to use a multiple pass printing method with the same reagent using an inkjet dispensing head. One would have been motivated to do so to reduce serious error which include failure of a drop deposition unit in a multiple drop deposition unit system with the same reagent [Bass, column 3, lines 22-26] to a targeted area in any given cycle, while improving the accuracy of the projection of the reagent dispensing system when ejecting multiple (same) reagent droplets to form a desirable final product [Bass, column 4, lines 28-37].

8. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiratsuka et al. in view of Greenstein as applied to claim 1 above, and further in view of Dombrowski [US 5047206] and Naka [JP8247946].

Teachings of Hiratsuka et al. in view of Greenstein is aforementioned (e.g. having the capability of applied a material liquid to a targeted area). Hiratsuka et al. in view of Greenstein fails to teach the material liquid (containing the reagent) on the bottom surface is spaced from the side surface at a constant distance (claim 6), where the distance is no smaller than 0.1 micrometers (claim 7). Dombrowski and Naka teach these deficiencies.

Regarding claim 6, Dombrowski teaches a reagent test strip [abstract], in which a ceiling portion position over the reagent surface can be spaced 0.25-1 millimeters from the reagent surface where the space is critical [column 4, lines 27-31]. This is because the space acts as a capillary, and by capillary action the capillary chamber draws in a predetermined amount of liquid (sample) to directly and completely cover the reagent surface; it obtains a precise amount of liquid sample to evenly and completely cover the reagent surface to saturate the reagent [column 4, lines 37-45]. It would have been apparent to one with ordinary skill in the art that the space would be at a constant distance (as indicated by the specific distance) for an even submersion of the reagent in the drawn amount of liquid sample. In conjunction, Naka discloses a test piece for a reflectormeter, where, in light of the drawings, a reagent is seen placed in a center of the bottom surface with a consistent space between the bottom surface and the side surfaces of the reagent holding portion of the test piece [Naka, figure(s) 1]. It would have been obvious to one with ordinary skill to apply a reagent to area of the bottom surface spaced from the top surface *as well as from the side surface* at a constant distance to fully saturate the top *and the sides* of the reagent member. This would

Art Unit: 1792

ensure a more certain evaluation of determining the presence of an analyte in a liquid sample by optimize the usage of the reagent member. The constant space between the reagent and the side surface of the test piece would allow the liquid sample to complete surround and evenly submerge the reagent member to activate a complete reaction with the reagent member.

Regarding claim 7, Hiratsuka et al. in view of Greenstein further in view of Dombrowski and Naka, discloses a space is variable dependent upon the dimensions of a reagent for a particular test [column 4, lines 31-33], where the space between the reagent can be from 0.25-1 mm [column 4, lines 28], which is larger than 0.1 micrometers. This specific distance can be applied with the obviousness of maintaining a space between the reagent member and the side surfaces to ensure the liquid sample is fully in engaged (immersed) with the reagent member for analyte detection.

It would have been obvious to one with ordinary skill in the art at the time of the invention to apply Dombrowski and Naka with Hiratsuka et al. in view of Greenstein to maintain a constant space between the surface of the reagent from the top and side surfaces of the analytical tool. One would have been motivated to do so to entirely draw a predetermined amount of sample liquid to directly and completely cover the with the reagent member and saturate the reagent surface; therefore, no excess liquid sample is required other than that necessary to cover the reagent surface [Dombrowski, column 4, lines 34-44]. One would have been motivated to maintain a space between the side surfaces and the reagent to have a liquid sample react with more surface areas of the

Art Unit: 1792

reagent member to further increase the contact of the reagent to the analyte in the liquid sample, and subsequently yielding a better determination of the analyte presence.

9. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiratsuka et al. in view of Greenstein as applied to claim 5 above, and further in view of Taguchi et al. [US 5681529].

Teachings of Hiratsuka et al. in view of Greenstein is aforementioned. Hiratsuka et al. in view of Greenstein fails to teach the recess (reagent holding portion) has a depth ranging from 50-200 micrometers (claim 8), where the recess has a volume ranging from 0.05-5 microliters (claim 9). Taguchi et al. teach these deficiencies.

Regarding claims 8 and 9, Taguchi et al. teaches a biological fluid analyzing device [abstract], where sizes of the regions in the analyzing device is described having a height (depth) of the pathway and chamber regions (recess) of 100 micrometers [column 10, lines 65-67]; where a reagent is applied in sample-treating chamber (2b) to react with the liquid sample [column 6, lines 11-12]. Taguchi et al. also teaches the volume of the sample-treating chamber (2b) is 20 microliters [column 11, lines 11-12]. In addition, Taguchi et al. discloses that there are no restrictions on size shape or material of the analyzing device as one could modify the design for specific test needs [column 5, lines 8-13]. It would have been obvious to one with ordinary skill in the art that the sample-treating chamber (recess) is capable of having a volume of 0.05- 5 microliter by adjusting *the width and, or length* of the recess to fit the size of any type of reagent member.

It would have been obvious to one with ordinary skill in the art at the time of the invention to apply Taguchi et al. with Hiratsuka et al. in view of Greenstein to have a recess that has a depth ranging from 50-200 micrometers and a volume ranging from 0.05-5 microliters. One would have been motivated to do so to manufacture an analyzing device which requires less reagent material to reduce material costs. And while still obtaining a high level of precision in analyzing a liquid sample and be disposable that can be discarded after use [column 3, lines 47-48].

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiratsuka et al. in view of Greenstein as applied to claim 1 above, and further in view of Demers [US 6117396].

Teachings of Hiratsuka et al. in view of Greenstein is aforementioned. Hiratsuka et al. in view of Greenstein fails to teach the amount of material liquid applied ranges from 1-200nL. Demers teaches this deficiency.

Regarding claim 12, Demers teaches a device for delivering defined volumes such as reagent [abstract], where the device can deliver a 8 nL or more volume to an analytical piece [column 9, lines 40-41]. It would have been apparent to one with ordinary skill in the art to modify the dispensing device (e.g. nozzle) to deliver a predetermined amount of reagent necessitated by the analytical device for a particular purpose.

It would have been obvious to one with ordinary skill in the art at the time of the invention to apply Demers with Hiratsuka et al. in view of Greenstein to dispense a range of material liquid from 1-200 nL. One would have been motivated to do so to

Art Unit: 1792

control the amount of material liquid dispensed to accurately coat the region designated for the reagent member. As well as quickly distributing the material liquid to the appropriate location, while be able to reduce wasting reagent material.

11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiratsuka et al. in view of Greenstein as applied to claim 13 above, and further in view of Matsushita [JP410214772A].

Teachings of Hiratsuka et al. in view of Greenstein are aforementioned. Hiratsuka et al. in view of Greenstein fails to teach to applying radiant heat above the material liquid. Matsushita teaches this deficiency.

Regarding claim 14, Matsushita teaches a substrate heating treating device by providing an upper hot plate with a heat exchanger above a substrate, where radiant heat is transferred from the upper hot plate to the heat exchanger to radiate upon the substrate [abstract]. It would have been apparent to one with ordinary skill in the art that the substrate is capable of containing a film or liquid material containing a reagent for drying since there is a layer of air spaced between the heat exchanger and substrate; therefore, giving another reason for the heat treatment.

It would have been obvious to one with ordinary skill in the art at the time of the invention to apply Matsushita with Hiratsuka et al. in view of Greenstein to apply radiant heat above the surface containing material liquid. One would have been motivated to do so for uniform temperature (heat) distribution to the surface [Matsushita, abstract], which consequently improve uniform drying of the material liquid onto the surface.

Art Unit: 1792

12. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiratsuka et al. in view of Greenstein as applied to claim 1 above, and further in view of Rickerby et al. [US 5656364].

Teachings of Hiratsuka et al. in view of Greenstein is aforementioned. Hiratsuka et al. in view of Greenstein fails to teach a thin layer having a thickness ranging from 0.1-5 micrometers is formed at each coating application step, where the total thickness of all the layers ranges from 1-50 micrometers. Rickerby et al. teaches this deficiency.

Regarding claim 12, Rickerby et al. teaches a multiple layer coating on a substrate [abstract], where the prior art exemplified each layer is 1 micrometer in thickness, and the total thickness of the multiple layer coating is 50 micrometers [column 3, lines 60-65; column 4, line 5].

It would have been obvious to one with ordinary skill in the art at the time of the invention to apply Rickerby et al. with Hiratsuka et al. in view of Greenstein to apply each thin film with a thickness ranging from 0.1-5 micrometers producing a multiple layer coating with a final thickness ranging from 1-50 micrometers. One would have been motivated to do so to improve the multiple layer coating by applying thin layers at the micro-scale to provide resistance to erosion [Rickerby et al., 31-33], whether the erosion is caused by the diffusion of the liquid sample when place in contact with the reagent member, so the improved erosion resistance allows the analyte detection with the reagent to occurs in the targeted region of the analytical tool. In addition, by applying thin layers of the coating material, this allows the final multiple layer coating to be uniform in structure.

Art Unit: 1792

13. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiratsuka et al. in view of Greenstein as applied to claim 1 above, and further in view of Bruschi et al. [US 4066403].

Teachings of Hiratsuka et al. in view of Greenstein is aforementioned. Hiratsuka et al. in view of Greenstein fails to teach a reagent member formed by a stack of plurality of reagent layers containing different reagent. Bruschi et al. teaches this deficiency.

Regarding claim 17, Bruschi et al. teaches an analytical element for assay which comprises two reagents [abstract], where the reagents with different functions [column 3, lines 42-50] are stacked in a multi-layer formation [column 5, lines 18-19] and as shown in figures.

It would have been obvious to one with ordinary skill in the art at the time of the invention to apply Bruschi et al. with Hiratsuka et al. in view of Greenstein to stack a plurality of reagent layers containing different reagents to form a reagent member. One would have been motivated to do so to provide a analytical element that is protected against the intrusion of undesirable alternative reactive materials that could falsify the readings [column 3, lines 24-28], in addition to detecting a multiple of analytes from a single liquid sample.

14. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiratsuka et al. in view of Greenstein as applied to claim 1 above, and further in view of Sakota et al. [US 5178831].

Teachings of Hiratsuka et al. in view of Greenstein is aforementioned. Hiratsuka et al. in view of Greenstein fails to teach the reagent member comprises an assembly of separate reagent members containing different reagents (claim 18) and the analytical tool comprises a plurality of reagent members containing different reagents spaced from each other in a plane (claim 19). Sakota et al. teaches these deficiencies.

Regarding claim 18, Sakota et al. teaches a device for testing body fluids [abstract], where the device may comprise an assembly of separate reagent members containing different reagents [column 15, lines 18-31; figures 7 & 8].

Regarding claim 19, Sakota et al. teaches the analytical device comprising a plurality of reagent members containing different reagents spaced from each other [column 15, lines 18-31; figures 7 & 8]. In light of the figures provided by Sakota, it would have been apparent to one with ordinary skill in the art that the reagent members would be spaced from each other in a plane to have multiple reagents reacting with the liquid sample without interfering with the other reagent members while maintaining the flat plate like structure for the analytical device.

It would have been obvious to one with ordinary skill in the art at the time of the invention to apply Sakota et al. with Hiratsuka et al. in view of Greenstein to have an assembly of separately spaced reagent member in the same plane of the analytical device. One would have been motivated to do so to fabricate a single device that is capable of conducting multiple readings of the liquid sample [column 41-46] in an accurate manner [column 27, lines 62-63] and increase the exposures of the reagent

Art Unit: 1792

members to the liquid sample in a uniformed manner by assembling the reagent members in a plane.

Conclusion

1. No claim is allowed.
2. Claims 1-19 are rejected for the reasons aforementioned.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MANDY C. LOUIE whose telephone number is (571)270-5353. The examiner can normally be reached on Monday to Friday, 7:30AM - 5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on (571)272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/537,391
Art Unit: 1792

Page 18

/M. C. L./
Examiner, Art Unit 1792

/Timothy H Meeks/
Supervisory Patent Examiner, Art Unit 1792